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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,431	01/03/2007	**Gerhard Tivig**	PHDE030358US	9506

38107 7590 09/19/2008

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
595 MINER ROAD
CLEVELAND, OH 44143

EXAMINER	
BITAR, NANCY	
ART UNIT	**PAPER NUMBER**
2624	
MAIL DATE	**DELIVERY MODE**
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,431	TIVIG ET AL.	
	Examiner	Art Unit	
	NANCY BITAR	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10,12 and 14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10,12 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, in the amendment filed 06/25/2008, with respect to the rejections of claims 1-4,6-9,11-13,16-19 under 35 U.S.C. 102(b) have been fully considered but are moot in view of the new ground(s) of rejection necessitated by the amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Zaleski et al (US 2003/0149597), The 112 rejection of claim 12, 16-17 has been withdrawn.

Examiner Notes

2. Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

> Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.
>
> When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).
>
> In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

3. Claim(s) 7-10, 23 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 7-10defines a "computer programmed to perform the method" embodying functional descriptive material. Claim 23, teaches a medical monitoring device comprising "a computer programmed to receive". However, the claim does not define a computer-readable medium or memory and is thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" – Guidelines Annex IV). That is, the scope of the presently claimed "a computer program" can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The examiner suggests amending the claim to embody the program on "computer-readable medium" or equivalent in order to make the claim statutory. Any amendment to the claim should be commensurate with its corresponding disclosure

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2-10, 12, 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seely et al (US 2003/0117296) in view of Zaleski et al (US 2003/0149597).

As to claim 5, Seely et al teaches the method of automatically displaying medical measurement data in which a computer: receives the medical measurement data (107, figure 1) automatically converts in real time the received measurement data into data for histograms (paragraph [0075], [0085]), during the conversion, generates a cumulative curve indication of the medical measurement data (figure 5, and 6) and outputs the cumulative curve combined with the histogram as picture signals signals (paragraph [0088-0089]). While Seely et a meets a number of the limitations of the claimed invention, as pointed out more fully above, Seely teaches the variability display (paragraph [0085-0090] but fails to specifically teach generates a cumulative curve indication of the medical measurement data and outputs it together with the converted data combined as picture signals. Specifically, Zaleski et al teaches in FIG. 3 a data histogram showing comparisons between inpatient age distributions for various patient data populations and in figure 4 a comparisons between inpatient charge distributions for various patient data populations .Zaleski et al illustrate in figure 6 the cumulative distribution curves for five

diagnoses from breast biopsies after creating the histogram in figure 5 by showing a comparison between inpatient and outpatient charges, showing a 1-sigma standard deviation for five breast biopsy diagnoses. It would have been obvious to one of ordinary skill in the art to generate a cumulative curve and outputs it with the histogram in Seely display in order to facilitate the indication and the precise evaluation of the medical measurement data

As to claim 2, Seely et al teaches a method as claimed in claim 5, further including dynamically updating in real-time the histogram and the cumulative curve (These values can be displayed as pairs of dynamic variability parameter histograms 526, 546, figure 5).

As to claim 3, Seely et al teaches a method as claimed in claim 5, further including: filing the histogram is filled with measurement data from a time window advancing in real time with selectable fixed length (see figure 6, note that for each patient parameter v.sub.k, a user, typically an attending physician, may select the number of data points m.sub.k to collect in order to perform the variability analysis).

As to claim 4, Seely et al teaches a method as claimed in claim 2, wherein, during the conversion, the computer generates aids for the retrospective analysis of histograms in the form of selectable functions that can be displayed on a viewing screen and outputs them together with the converted data combined as picture signals (note that the process 110 may be selected by a user from among a plurality of variability analysis options using a user interface 117, see paragraph [0061]).

As to claim 6, Seely et al teaches a method as claimed in claim 1, wherein the computer processes control signals that are produced by input means communicating with the computer

and that serve to control the conversion and/or the output of the picture signals ,(The known individual patient interface and display 106a communicates measured values of the patient parameters to an apparatus in accordance with the invention that includes a processor 107 that performs individual patient data collection 108, paragraph [0061]) .

The limitation of claims 7-8 has been addressed above.

As to claim 9, Seely et al teaches a device, for automatically displaying medical measurement data comprising the computer is designed to generate, during the conversion, aids for the retrospective analysis of histograms in the form of selectable functions (variability analysis specified by a user who selects specifications from a plurality of pre-defined methods; and continuous display of multiple variability analyses in real time, while permitting user-specified selection of patient parameters, patients and choice of variability analysis, Paragraph [0030]) .

The limitation of claim 12 has been addressed in figure 5 of Seely, 502.

Seely teaches the limitation of claim 14 wherein the retrospective analysis aids include a deviation readout (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate

distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083])

Seely teaches the limitation of claim 15 in paragraph [0108].

As to claim 16, Seely et al teaches the medical monitoring device as claimed in claim 15 further comprising an alarm indicator that is triggered measurement of histogram data is measured above or below a lower or upper alarm limits, (Alarms can be set so that if a variability histogram is within the normal range, it is displayed in one color (green, for example). If the value of the histogram rises above or falls below the normal range, it is displayed in a different color (red, for example), paragraph [0089]).

As to claim 17, Seely et al teaches the medical monitoring device as claimed in claim 13, wherein the histogram data is binned into histogram bins, the histogram bin size being definable by the user (The data is plotted in frequency bins, where each bin represents a proportional amount of variation, as measured by the squared difference from the mean, paragraph [0085]).

As to claim 18, Seely et al teaches the medical monitoring device as claimed in claim 13 further comprising display means for displaying real-time signal patterns of the medical measurement data (real-time display, 502, figure 5).

As to claim 19, Seely et al teaches the medical monitoring device as claimed in claim 18, wherein the real-time signal patterns and the histogram data are displayed next to one another on the display means (figure 5, 6; note that the variability analysis may be displayed on a

multiple patient display at a central ICU console, as well as individual patient displays, paragraph [0108])

The limitation of claim 20-23 has been addressed above. Note that Zaleski teaches the cumulative curve in figure 6 and Seely teaches the clinical therapeutic potential of this invention is the ability to distinguish pathologic from physiologic systemic properties by monitoring patterns of alterations in the variability of multiple patient parameters. Thus a display can be tailored to best represent the current state of any individual patient with a view to evaluating the physiologic and pathologic properties of individual organ systems, by following the variability of parameters intrinsic to that system. Moreover, Seely teaches the beneficial to distinguish between organ systems, because therapeutic intervention is commonly directed towards individual organs. Examples of organ systems include the cardiovascular system, respiratory system, the hematological system, central nervous system, liver and metabolic system, kidney and waste excretion system in order to provide flexibility in the display of variability of multiple parameters. The user may select various display options to profile an organ system or a combination of interdependent organ systems(paragraph [0091-0093]).moreover, Seely teaches retrospective analysis aids include a percentage of time that histogram values are within limits defined by the range-selection cursors; a variability/stability readout that provides information about variability of the measurement data (Normal" ranges for the variability of each patient parameter for each patient can be determined by analysis over time, paragraph [0089]).

The limitation of claims 22-23 has been addressed above.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jinge Wu can be reached on 571-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nancy Bitar 9/15/2008

/Samir A. Ahmed/
Supervisory Patent Examiner, Art Unit 2624